

## Message Text

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PAGE 01 STATE 224280

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ORIGIN HEW-06

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DRAFTED BY DHEW/FDA:JRWEINROTH, M.D.

APPROVED BY OES/APT/BMP:MBEAUBIEN

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R 192207Z SEP 75

FM SECSTATE WASHDC

TO AMEMBASSY BRUSSELS

AMEMBASSY BONN

AMEMBASSY THE HAGUE

UNCLAS STATE 224280

E.O. 11652: N/A

TAGS: OGEN, OTRA, TBIO, BE, GW, NL

SUBJECT: FDA REPRESENTATIVES PROVIDING TECHNICAL AND CONSULTATIVE ASSISTANCE TO MANUFACTURERS OF DIAGNOSTIC X-RAY EQUIPMENT.

1. FDA ADVISES THAT MR. ROBERT G. BRITAIN, DIRECTOR, DIVISION OF COMPLIANCE; DR. ROYCE L. GRAGG, CHIEF, MEDICAL PRODUCTS SECTION, X-RAY PRODUCTS BRANCH, DIVISION OF COMPLIANCE; AND DR. ROBERT M. GAGNE, RECORDS AND REPORTS REVIEW OFFICER, X- RAY PRODUCTS BRANCH, DIVISION OF COMPLIANCE, BUREAU OF RADIOLOGICAL HEALTH WILL BE IN EUROPE SEPTEMBER 27 - OCTOBER 11, 1975.
2. THE BUREAU OF RADIOLOGICAL HEALTH, FDA HAS BEEN GIVEN THE AUTHORITY UNDER THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT, THE RESPONSIBILITY TO DEVELOP AND ADMINISTER PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS WHICH HAVE THE POTENTIAL TO PRODUCE RADIATION. THE BUREAU OF RADIOLOGICAL HEALTH AS PUBLISHED A PERFORMANCE STANDARD IN THE FEDERAL REGISTER FOR DIAGNOSTIC X-RAY EQUIPMENT USED IN THE HEALING ARTS. THE STANDARD BECAME EFFECTIVE ON AUGUST 1, 1974. AS A RESULT OF THIS STANDARD, AND IN CONJUNCTION WITH THE REGULATIONS PUBLISHED PURSUANT TO THE ACT,  
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PAGE 02 STATE 224280

MANUFACTURERS ARE REQUIRED TO CERTIFY THAT THEIR PRODUCTS COMPLY

WITH THE PERFORMANCE STANDARD. THE MEMBERS OF THE TEAM ARE PREPARED TO DISCUSS SPECIFIC TECHNICAL RAMIFICATIONS OF THE STANDARD AS WELL AS THE POLICY AND PROCEDURAL REQUIREMENTS PLACED UPON FOREIGN MANUFACTURERS. IN ADDITION, THE QUALITY CONTROL AND TESTING PROGRAMS BEING UTILIZED BY THE MANUFACTURER TO ASSESS THE RADIATION EMISSIONS AND TO ASSURE COMPLIANCE WITH THE REQUIREMENTS OF THE PERFORMANCE STANDARD WILL BE DISCUSSED. IT IS ENVISIONED THAT AS A RESULT OF THESE ON-SITE CONSULTATIONS, THE IMPORTATION OF FOREIGN DIAGNOSTIC X-RAY EQUIPMENT WHICH MUST ADHERE TO THE PROVISIONS OF THE ACT WILL BE FACILITATED.

3. ITINERARY AS FOLLOWS:

SEPTEMBER 26, 1975 - DEPART ROCKVILLE, MD. FOR AMSTERDAM, NETHERLANDS  
SEPTEMBER 28 - TRAVEL TO DELFT, NETHERLANDS  
SEPTEMBER 29 - VISIT N. B. OPTISCHE INDUSTRIE  
SEPTEMBER 29 - TRAVEL DELFT, NETHERLANDS TO ANVERS, BELGIUM  
SEPTEMBER 30 - VISIT CGR MEDICAL CORPORATION  
SEPTEMBER 30 - TRAVEL ANVERS, BELGIUM TO ESSEN, W. GERMANY  
OCTOBER 1 - VISIT CGR MEDICAL CORPORATION  
OCTOBER 2 - TRAVEL ESSEN TO ERLANGEN, W. GERMANY  
OCTOBER 3 AND OCTOBER 6 - VISIT SIEMENS CORPORATION  
OCTOBER 6 - TRAVEL ERLANGEN TO HAMBURG W. GERMANY  
OCTOBER 7 AND 8 - VISIT PHILIPS MEDICAL SYSTEMS  
OCTOBER 8 - TRAVEL HAMBURG, W. GERMANY TO EINDHOVEN, NETHERLANDS  
OCTOBER 9 AND 10 - VISIT PHILIPS MEDICAL SYSTEMS  
OCTOBER 10 - TRAVEL EINDHOVEN TO AMSTERDAM, NETHERLANDS  
OCTOBER 11 - DEPART AMSTERDAM, NETHERLANDS FOR ROCKVILLE, MD.

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED.  
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**TAGS:** OGEN, OTRA, TBIO, BE, GE, NL, FDA, (BRITAIN, ROBERT G), (GRAGG, ROYCE L),  
**To:** BRUSSELS THE HAGUE  
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